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6/2/97

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food & Drug Administration
1141 Central Parkway
Cincinnati, OH 45202

May 28, 1997

WARNING LETTER
CIN-WL-97-369

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Eugenia M. Guseila,
General Manager
Allied Healthcare Products, Inc.
1421 Expressway Dr., N.
Toledo, Ohio 43608

Dear Ms. Guseila:

The Food and Drug Administration (FDA) conducted an inspection on April 29 - May 2, 1997 of your firm that manufactures respiratory therapy devices. These are devices as defined by Section 201(h) of the Federal Food, Drug and Cosmetic Act (the Act).

The above-stated inspection revealed that these devices are adulterated within the meaning of Section 501(h) of the Act, in that the methods used in, or the facilities or controls used for manufacturing, packing and storage are not in conformance with the Good Manufacturing Practice (GMP) for Medical Devices Regulation, as specified in Title 21, Code Of Federal Regulations (CFR), Part 820. The inspection also revealed that some of the devices such as the Aero Mist Nebulizer Sets are misbranded within the meaning of Section 502(b) and 502(f) of the Act in that individual set bags lacked the name and place of business of the manufacturer; directions for use and the prescription legend.

The following deviations from Device GMP's were documented;

- Failure to conduct planned and periodic audits of the quality assurance program in accordance with written procedures.

- Failure to provide proper label storage in that labels with the BF logo (Part FM10002) and with no BF logo (Part NC1017) were stored mixed together on a shelf marked for Part #FM1002.. Part FM10002 is the label for the Aero Mist Nebulizer Sets.
- Failure to review returned goods forms to determine if they represent complaints - For example; In the last year there were at least 18 returned goods reports that were possible complaints that were not investigated.

- Failure to calibrate current measurement equipment and to maintain a record of the last date of calibration - For example, No records could be found for the [redacted] scale used to weight the corrugated aerosol tubing.

- Failure to follow the incoming inspection standard operating procedures for raw materials in that a shipment of 33 pallets of PVC used to make 61400 tubing was accepted without a Certificate of Analysis.

- Failure to document engineering changes in the device master record and device history record.

This letter is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure adherence to each requirement of the Act and regulations. The specific violations noted in this letter and in the FDA 483 issued at the closeout of the inspection may be symptomatic of serious underlying problems in your firm's manufacturing and quality assurance systems. You are responsible for investigating and determining the causes of the violations identified by the FDA. If the causes are determined to be systems problems, you must promptly initiate permanent corrective actions. We are especially concerned that an incorrect labeled product was released for distribution.

Federal agencies are advised of the issuance of all Warning Letters about devices so that they may take this into account when considering the award of contracts. Also, no requests for Certificates For Products For Export will be approved until the violations related to the subject devices have been corrected.

You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action being initiated by the Food and Drug Administration without further notice. These actions include, but are not limited to, seizure, injunction, and/or civil penalties.

We acknowledge your letter of May 12, 1997 and attachments which cover corrections you made in response to Form FDA-483.

We also acknowledge the letter dated May 23, 197 by James Spillis, Manufacturing Manager which covered labeling changes. We also believe that the package labeling should contain directions for use.

Please notify this office within 15 days of receipt of this letter, of additional steps you have taken or corrections that you have completed to comply with the FDA-483 and this letter.

Your response should be sent to Lawrence E. Boyd, Compliance Officer, Food and Drug Administration, 1141 Central Parkway, Cincinnati, Ohio 45202.

Sincerely,

John R. Marzilli
District Director
Cincinnati District

LEB/clc

cc: UMA Nandan Aggarwal, President
Allied Healthcare Products, Inc.
2085 Rustin Avenue
Riverside, California 92507-2437